UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**Oral Argument Requested**

MEMORANDUM OF LAW IN SUPPORT OF MANUFACTURER AND PHARMACY DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF DR. RENA CONTI

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PRELIMINARY STATEMENT

Dr. Rena Conti purports to offer classwide damages models in support of Plaintiffs' proposed economic loss and third-party payor ("TPP") classes. As set forth below, Dr. Conti's models are contrary to basic economic principles and realities—and are therefore inadmissible under Fed. R. Evid. 702 and *Daubert*.

First, Dr. Conti's damages models are unreliable because they proceed from the demonstrably false premise that the Valsartan-containing drugs ("VCDs") at issue in this litigation had zero value. Statements by the U.S. Food & Drug Administration ("FDA") and several of the named Plaintiffs make it crystal clear that the VCDs had value—and that their value differed from one person to another. Dr. Conti offers no valid medical or economic basis to defend her contrary and counterfactual position. For this reason alone, all of her opinions should be excluded.

Second, Dr. Conti's damages opinions should separately be excluded because she bases her calculation exclusively on the money that changes hands at the point of sale. This overly simplistic approach does not reliably measure amounts paid by putative class members because it ignores a maze of pre- and post-sale government subsidies, fees, and refunds that drastically alter and offset the point-of-sale spending, resulting in an inaccurate depiction of costs that may have been incurred by consumers and TPPs.

Finally, Dr. Conti's unjust enrichment opinion (which applies only to the

Pharmacy Defendants, not the Manufacturers) is unreliable because she proposes to calculate pharmacy profits simply by adding up all consumer payments for valsartan. Although Dr. Conti purports to subtract "costs" from revenues, her definition of costs *excludes* the actual cost of valsartan, which is tantamount to assuming that pharmacies received valsartan for free.

BACKGROUND

Dr. Conti currently works as an associate professor at Boston University and an affiliate of a "consulting and litigation support firm." Ex. 1, Expert Decl. of Rena Conti, Ph.D. ("Conti Decl.") ¶ 12, Nov. 10, 2021. She receives approximately a quarter of her income from work as an expert witness, generally for plaintiffs. *See* Ex. 2, Dep. of Rena M. Conti, Ph.D., Vol. I ("Conti Dep. I") 24:2-25:2, 26:4-17, Feb. 10, 2022. Dr. Conti seeks to "provide opinions and calculations regarding the injury and damages incurred by [putative c]lasses of consumers and [third-party] payors" ("TPPs").[1] Conti Decl. ¶ 1.

"***No Value" Assumption.*** At the heart of Dr. Conti's model, and of her opinion, lies the assumption that all of the VCDs at issue in this litigation "have no economic value[] [and] . . . are worthless." *Id.* ¶ 7. Dr. Conti bases that assumption on an instruction from Plaintiffs' counsel. According to her deposition testimony, she was "asked to assume" that: (1) the VCD "products were adulterated and

[1] Dr. Conti generally refers to third-party payors as "end payors."

misbranded"; (2) "there is no supply that is legitimate for these products . . . as a matter of U.S. policy"; and (3) as a result, "there can be no price." Conti Dep. I 183:2-7. Strikingly, Dr. Conti acknowledges that even batches of the VCDs "without the [alleged] impurity" are assumed to be worthless under her methodology as long as they were manufactured by a defendant within the relevant time period. Ex. 3, Dep. of Rena M. Conti, Ph.D., Vol. II ("Conti Dep. II") 158:19-25, Feb. 11, 2022. Dr. Conti testified that "[w]hether those products provided therapeutic value . . . doesn't matter," and that VCD medications that prevented a heart attack or stroke still "d[id]n't have economic value." Conti Dep. I 137:15-138:15. Thus, contrary to common sense, her definition of the economic value of a prescription drug excludes its capacity to protect human health. *See id.* 146:17-24 ("Therapeutic value, whether th[e] product . . . provides value or clinical value or maybe does have some economic value to a consumer . . . goes above and beyond the economic value that I have been asked to consider."). Nor does her opinion turn on standard economic considerations such as whether individual consumers or TPPs "would have paid the same or more for [a] different drug" had the VCDs not been on the market. *Id.* 198:25-199:23.

To justify her counterintuitive definition of worthlessness, Dr. Conti concocts an artificial supply and demand chart on which she has erased the supply curve, on the ground that it is "illegitimate." Dr. Conti opines that "[a]ccording to economic theory," value is set by the intersection of a demand curve and a supply curve, where

the equilibrium price is found. Conti Decl. ¶ 43 & fig. 1. She then refuses to draw a supply curve for what she terms "non-safety and quality compliant . . . drugs," because, in her opinion, they "should not be available for sale in the United States." *Id.* ¶ 44. Dr. Conti's erasure of the supply curve yields "no equilibrium between the demand . . . and the supply" and therefore "no economically determinable price." *Id.* & fig. 2. Dr. Conti attempts to rationalize her opinion with her subjective views on optimal public policy, asserting that "assigning a non-zero value to non-safety and quality compliant products [would be] perverse . . . [and] incentivize . . . cheating." *Id.* ¶ 45. At her deposition, Dr. Conti also offered a new justification—***fed to her via text message by Plaintiffs' counsel***—that one of the Court's motion-to-dismiss rulings justifies her expert opinions. Conti Dep. I 153:10-155:20.

Dr. Conti offers separate opinions with respect to "liability" damages for Manufacturers and Pharmacies and "unjust enrichment" damages for Pharmacies.

Liability Damages. Dr. Conti seeks to opine that "liability" damages are equal to "the total dollar amount paid" for VCDs. Conti Decl. ¶ 56. Even if her assumption that the VCDs were valueless had any validity, this measure of damages would be overly simplistic. As defense expert Timothy Kosty has explained—and no Plaintiffs' expert disputes—cost structures for individual consumers and especially TPPs are influenced by government subsidies, dispensing fees, renumeration fees, claims reversals, post-sale refunds, and more. *See generally* Ex. 4, Expert Rep. of

Timothy Kosty ("Kosty Rep."), Jan. 12, 2022. Dr. Conti acknowledges these factors and concedes that she does not, and cannot, account for any of them. *See, e.g.*, Conti Decl. ¶ 56 n.52 ("I do not consider offsets . . . ."); Conti Dep. I 225:5-8 ("Whether or not there [were] side payments or subsidies or anything else that [plaintiffs] may face[] is of no moment to my economic analysis."); Conti Dep. II 36:20-22 ("[T]here are significant limitations in the claims data that w[ere] provided to me."). Instead, she seeks to avoid complexities by erroneously defining "economic price" to be limited solely to "the price . . . at the point of sale." Conti Decl. ¶ 56. But this shortcut is not an accurate way to assess whether economic *loss* occurred, and if it did, how to quantify it.

Dr. Conti's overly simplistic model effectively reduces her damages calculation to simple multiplication. In her words, she "total[s] the quantity of at-issue [VCDs] purchased by class plaintiffs and multipl[ies] it by the [point-of-sale] cost incurred." *Id.* ¶ 57. Dr. Conti began by purchasing "IQVIA Xponent data," which contain "summaries of pharmaceutical claims," including the "full cost" paid. *Id.* ¶ 71. To value the consumer class claims, Dr. Conti multiplies the full cost paid for insured customers by "the average copayment/coinsurance" rate, "calculate[s] the full quantity and price" spent by "cash-paying customers," and then adds the two together. *Id.* ¶¶ 72-74. For the TPP class claims, she excludes prescriptions paid at

the point of sale in cash or by certain government programs[2] and then subtracts "the average copayment/coinsurance" rates from what remains. *Id.* ¶¶ 75-77. At no point does Dr. Conti consider payments such as subsidies, fees, or refunds.

Unjust Enrichment Damages. With respect to unjust enrichment damages, which are not sought from the Manufacturer Defendants, Dr. Conti simply claims to calculate the Pharmacy Defendants' profits, as set forth in Supplemental Table 3.[3] Conti Dep. II 169:15-20 ("Q. Dr. Conti, the dollar figures reflected in Table 3 for unjust enrichment damages represent your calculation of the profits each pharmacy defendant had from the sale of at-issue valsartan, right? A. Correct."). As with the Manufacturers, Dr. Conti calculated these figures solely at the point of sale. *See* Conti Decl. ¶ 63.

To derive what she labels pharmacy "profits," Dr. Conti adds the total amount of patient co-payments for each Pharmacy Defendant in each applicable state and

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[2] Dr. Conti excludes payments made directly by the government "based on instruction from counsel." Conti Dep. I 219:22-23. She does *not* exclude prescriptions paid by private plans at the point of sale that are subsidized or reimbursed by the government. The most notable examples are Medicare Advantage or Medicare Part D plans.

[3] On April 1, 2022, Plaintiffs served Defendants with Dr. Conti's Supplemental Expert Declaration. Although she modified some of her final damages calculations as to some of the Pharmacy Defendants based on "additional retailer claims data," Dr. Conti's methodology, as described in this motion, remained unchanged. *See* Ex. 5, Suppl. Decl. of Rena Conti, Ph.D. ¶ 2, Mar. 31, 2022 (noting "[a]s [she] described in [her] original report, [she] calculated Defendant Retailer . . . unjust enrichment damages using Defendant Retailer pharmacy claims data").

then lists that total in her pharmacy unjust enrichment table. Conti Dep. II 48:13-19 ("All I did was take the information that was provided to me by the at-issue retailers for the relevant time periods, the relevant manufacturers and the relevant product categories, and matched them with the states relevant for the unjust enrichment damages and summed them up.").

Dr. Conti claims that her profit calculation offsets some costs because the pharmacies removed dispensing "fees" from the data they produced about consumer payments. *Id.* 22:13-21; *see also id*. 50:3-7. In other words, because the data the pharmacies produced in discovery did not include a column specifically listing "dispensing fees," Dr. Conti assumed that the entire cost of dispensing valsartan had already been accounted for.

Dr. Conti admits that the mechanics of her calculation are different from what they should be from a "theoretical perspective." *Id.* 64:10. Indeed, she acknowledges that "other offsets may be removed from gross profits" beyond the dispensing fee she claimed had already been removed. Conti Decl. ¶ 65 n.64; *see also* Conti Dep. II 64:10-15 ("[U]njust enrichment should account for the cost of dispensing that prescription, which might be captured by the dispensing fee, but might have additional costs on top of it."). Dr. Conti offers no method to assess what those additional relevant costs would be, or how she or anyone attempting to calculate profits would begin to obtain them, asserting instead that her calculation of profits

"at the point of sale" renders the pharmacy cost to acquire the drug irrelevant to profits. Conti Dep. II 172:22-173:13.

ARGUMENT

The standards governing the admissibility of expert testimony are set forth in Defendants' Memorandum of Law in Support of Motion to Exclude Opinions of Dr. Edward H. Kaplan, M.D., and incorporated fully herein. Dr. Conti's opinions are inadmissible under these standards.[4]

I. DR. CONTI'S OPINIONS ARE UNRELIABLE BECAUSE THEY REST ON THE HIGHLY FLAWED PREMISE THAT THE VCDS HAD NO VALUE.

All of Dr. Conti's opinions share the same fundamental problem: her unsupported assertion that because some of the VCDs were allegedly impure, "there is no economically determinable price for [them]," and "they are worthless." Conti Decl. ¶ 44; *id.* at p. 16. This opinion is not based on any recognizable economic standards or reliable foundation and is contrary to law and logic.

[4] Defendants acknowledge that similar opinions regarding worthlessness and liability damages were found to be admissible in *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, No. 13-4663, 2019 WL 4751883, at *8-9 (E.D. Pa. Sept. 30, 2019). But the *Blue Cross* court abdicated its "rigorous" gatekeeping obligation, *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015), to ensure that all expert testimony is based on "sufficient facts or data," and "reliable principles and methods" that have been "reliably applied," Fed. R. Evid. 702. Instead, it simply opined, without serious analysis, that fundamental methodological errors could be dismissed as relevant to "weight" rather than "admissibility."

(cont'd)

Dr. Conti's opinion rests on her contrivance of a "legitimate" supply curve—a concept that she admits is based on *policy*, not economics. *See* Conti Dep. I 183:2-7 ("[T]herefore, there is no supply that is legitimate for these products as – **as a matter of U.S. policy**.") (emphasis added).[5] In addition, Dr. Conti's conclusion of worthlessness conflates price and value, which are not interchangeable concepts. *See* Chan Dep. 287:5-10. The most basic failure of Dr. Conti's analysis is that it does not measure economic loss, which is the "difference between the price paid and the value received." Stiroh Dep. 89:3-5. Dr. Conti's approach is also nonsensical in real-world terms. There *was* in fact a "legitimate" supply of FDA-approved VCDs at the time that they were sold, and consumers and TPPs paid economically determinable prices for those products and received valuable benefits in exchange.

As courts in this Circuit and elsewhere have explained, the failure to "account for any value" obtained from an allegedly defective product generally "render[s]" a damages "model unreliable and ill-fitting." *Center City Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 204 (E.D. Pa. 2017); *see Zeiger v. WellPet LLC*,

[5] As defense experts have explained, "legitimate supply" is not meaningful for assessing value from an economic perspective. *See* Ex. 6, Dep. of Lauren J. Stiroh, Ph.D. ("Stiroh Dep.") 179:1-3, Mar. 25, 2022; *id.* 176:7-20 ("The worth or value of drugs to consumers depends on their valuation of the products, not the supply of the products."); *see also* Ex. 7, Dep. of David C. Chan, Jr., M.D. ("Chan Dep.") 287:2-4, Mar. 3, 2022 ("[Y]ou can have value even if there's no market and even if there's no supply.").

526 F. Supp. 3d 652, 675-76 (N.D. Cal. 2021); *see also, e.g.*, *Medley v. Johnson & Johnson Consumer Cos.*, No. 10-cv-02291 (DMC)(JAD), 2011 WL 159674, at *2 (D.N.J. Jan. 18, 2011) (explaining, in the standing context, that plaintiffs had not suffered an economic injury by purchasing adulterated and illegal "shampoo, which they then apparently used . . . without adverse health reactions"). This is so because, under the substantive law of the great majority of states, "a full refund model is only justified when the plaintiffs prove the products have no value." *Zeiger*, 526 F. Supp. 3d at 675; *see also Jones v. Monsanto Co.*, No. 19-0102-CV-W-BP, 2021 WL 2426126, at *6 (W.D. Mo. May 13, 2021) (unjust enrichment "requires consideration of the fact that the consumers received and used" the product, and "received some value" from their purchase), *appeal pending*; *see generally* ECF 2008, Defs.' Mem. in Opp'n to Pls.' Mot. for Class Cert. of Consumer Econ. Loss Claims ("Econ. Loss Mem.") at 16, Apr. 12, 2022.

Dr. Conti does not and cannot dispute that many plaintiffs obtained substantial therapeutic value from their VCDs. The FDA expressly determined that the benefits of hypertension control outweighed any hypothetical health risks from potential impurities when it instructed patients that "[b]ecause valsartan is used in medicines to treat serious medical conditions, patients taking the recalled valsartan-containing medicines ***should continue taking their medicine*** until they have a replacement

product."[6] Many of the consumer class representatives likewise understood that their VCDs had therapeutic value and continued to take them even after the recall. *See* Econ. Loss Mem. at 14 n.79, Appx. D, E (quoting one plaintiff who took at-issue VCDs "[u]ntil [she] could get the medication changed because [she was] afraid not to take anything" because her "blood pressure [could] get[] out of control" and another who "continue[d] to take [her] valsartan until [she] picked up and [was] able to take losartan"). And Dr. Conti herself did not dispute "that th[e] products provided therapeutic value," i.e., that they improved the health of those who took them. Conti Dep. I 138:17-23. Further, 15 of the named Plaintiffs acknowledged that the VCDs were effective at managing their hypertension, with many testifying that VCDs were more effective than other blood pressure medications. *See* Econ. Loss Mem., Appx. D. [redacted]

The TPP plaintiffs also obtained substantial benefits from the at-issue VCDs alongside the consumers who took them. After all, consumers would still have had to purchase, and TPPs would "still have been obligated to cover[,] claims for unaffected VCDs or alternative hypertension medications," and those medications

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[6] FDA, "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity" (July 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity (emphasis added).

may well have been more expensive. Ex. 9, Rep. of Lauren J. Stiroh, Ph.D. ¶ 63, Jan. 12, 2022. If they did not pay for hypertension medications, the TPPs would have had to pay for the far more expensive consequences of untreated hypertension, such as heart attack or stroke. Again, Dr. Conti does not dispute this; instead, she simply asserts that "[w]hether consumers would have gone on to buy something else . . . is of no moment," and that the only relevant consideration is that "[p]eople bought things that . . . under the assumptions that were given to [her] . . . , should not have entered into the legitimate class of trade." Conti Dep. I 196:23-197:4.

The theory that any allegedly "adulterated and misbranded" medication is necessarily without value should also be rejected because it leads to illogical results. *See In re LIBOR-Based Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 467 (S.D.N.Y. 2018) ("[I]n assessing the reliability of an expert opinion, a resort to common sense is" appropriate.) (citation omitted). Dr. Conti concedes that a medication that saved a patient from heart attack or stroke would be "worthless" under her theory. *See* Conti Dep. I 137:15-138:15. In addition, her model would assign zero value to batches of medication that did not contain the alleged impurity. *See* Conti Dep. II 163:15-164:1. This approach would render worthless any product that happens to have trace levels of contaminants or technical labeling violations.[7]

[7] Dr. Conti's theory would also presumably assign zero value to the branded Reference Listed Drugs ("RLD") after which the at-issue VCDs were modeled, since *(cont'd)*

As the Third Circuit has explained, "[i]gnoring 'the real world'" can "render[] [an expert] opinion inadmissible." *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000). For this reason, courts have excluded expert opinions premised on the simplistic and doctrinaire insistence that "adulterated or misbranded products [necessarily] have no value as a matter of law." *Shahinian v. Kimberly-Clark Corp.*, No. CV 14-8390-DMG (PLAx), 2017 WL 11595343, at *11 (C.D. Cal. Mar. 7, 2017); *see Center City Periodontists*, 321 F.R.D. at 204 (excluding damages expert for presuming dental device was "worthless" and failing to credit "value obtained even with the alleged defect"). Courts have applied the same principle to reject class damages experts in closely related contexts at the certification stage. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (treating recalled diabetes drug as "worthless . . . is not a defensible position" because medication was "beneficial to many patients"); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 213 (D. Minn. 2003) (the court "cannot accept" that recalled medication "did not provide any benefit" where there was no dispute that it "effectively reduce[d] cholesterol").

Dr. Conti's resort to a policy rationale for her worthlessness theory should also be rejected because it is advocacy posing as expertise. Dr. Conti asserts that

there is evidence that some lots of the RLD contained NDMA impurities. (*See* Mem. in Supp. of Defs.' Mot. to Exclude Ops. of Ron Najafi, Ph.D. at 9-14 (filed contemporaneously herewith).)

"assigning a non-zero value" to Defendants' VCDs "is perverse" because it would "incentivize and legitimize cheating and non-compliance" and "undermine the substantial investments made" to protect patients. Conti Decl. ¶ 45. That is not an economic analysis. Needless to say, decisions regarding public policy are for legislatures, not expert witnesses. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 543 (S.D.N.Y. 2004); *see also Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 WL 1673805, at *8 (E.D. Pa. May 4, 2011) ("subjective views of ethics" are not "objective, reliable, scientific knowledge"). In any event, Dr. Conti's vision of public policy is contrary to the views of various courts, which have recognized that fully reimbursing patients for medications that did not harm them would result in overdeterrence and an improper windfall to uninjured consumers. As Judge Chesler explained in another prescription drug case, "if tort law fully compensates those who are physically injured, then any recoveries by those whose products function[ed] properly mean[] excess compensation." *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 379 (D.N.J. 2004) (quoting *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1017 (7th Cir. 2002)).

Finally, for the first time at her deposition, after receiving a text message sent to her by counsel mid-deposition,[8] Dr. Conti cited a snippet from the Court's ruling

[8] While Defendants have chosen not to press the point, it is clearly improper for counsel to text a witness the answer to a question. *Cf. Plaisted v. Geisinger Med.* *(cont'd)*

in Motion To Dismiss Opinion 3, 2021 WL 222776 (Jan. 22, 2021) ("MTD Op. 3"). *See* Conti Dep. I 153:10-154:13 (defining "economic worthlessness" "in the way that the judge in this case has defined" it and reading from MTD Op. 3). But MTD Opinion 3, which was not on Dr. Conti's reliance list, merely held that plaintiffs had adequately pled "at the motion to dismiss stage, [that] an [allegedly] adulterated [product] was worthless and had no value." MTD Op. 3, 2021 WL 222776, at *16. And the case on which the Court principally relied, *Debernardis v. IQ Formulations, LLC*, reinforced the importance of the procedural posture. *See* 942 F.3d 1076, 1085 (11th Cir. 2019) ("[W]e accept, at least at the motion to dismiss stage, that a [product] that is deemed adulterated . . . has no value."); *see id.* at 1090 (Sutton J., concurring) ("At summary judgment, each claimant will need evidence to back the point up. Why was the product worthless to each of them? How did it deliver less than expected? Did each of them use the product even after they knew of the labeling deficiency? The answers to these questions and others will determine whether the case may proceed further and, if so, how."). At this stage, the Court is no longer required to "accept all factual allegations as true," MTD Op. 3, 2021 WL 222776, at *8, but rather must determine whether Dr. Conti's no-value theory is based on a

Ctr., 210 F.R.D. 527, 533 (M.D. Pa. 2002) (quoting *Hall v. Clifton Precision*, 150 F.R.D. 525, 531-32 (E.D. Pa. 1993) (counsel may not make "statements which might suggest an answer" or "engage in private, off-the-record conferences" with witness)).

sound methodology and reliable. It is not.

For this reason alone, Dr. Conti's damages opinions should be excluded.

II. DR. CONTI'S LIABILITY OPINIONS ARE ALSO UNRELIABLE BECAUSE THEY FOCUS ONLY ON POINT-OF-SALE PAYMENTS.

Even if Dr. Conti could properly assert that the VCDs were worthless, her myopic focus on point-of-sale payments would still require exclusion of her opinions because she ignores a host of real-world factors that affect costs for consumers and TPPs. *See, e.g.*, *Mercedes-Benz USA, Inc. v. Coast Auto. Grp., Ltd.*, 362 F. App'x 332, 334 (3d Cir. 2010) (affirming exclusion of damages expert that ignored numerous relevant factors); *Smith v. Freightliner, LLC*, 239 F.R.D. 390, 393 (D.N.J. 2006) (similar); *Steven J. Inc. v. Landmark Am. Ins. Co.*, No. 1:14-CV-0474, 2015 WL 3849166, at *5 (M.D. Pa. June 22, 2015). At least one court in this Circuit has held that opinions that focus exclusively on point-of-sale damages to the exclusion of other factors are inadmissible "given the realities of the pharmaceutical industry." *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 146 (E.D. Pa. 2015). And other courts have found such models too weak to support class certification. *See, e.g.*, *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. 04-5898, 2010 WL 3855552, at *26 (E.D. Pa. Sept. 30, 2010) (rejecting opinion of expert who admitted that "some consumers or third-party payors, because of payment arrangements," would not have actually been injured) (citation omitted).

This Court should exclude Dr. Conti's opinions for similar reasons. Dr. Conti

admits that she "d[id] not consider offsets . . . [that] d[id] not occur at the point of sale." Conti Decl. ¶ 56 n.52. Indeed, she claims that "[w]hether or not there are side payments or subsidies or anything else" is of "no moment" to her economic analysis. Conti Dep. I 225:5-8. Only those transactions made "within seconds" of when "the pharmacy dispenses the product" count, in her opinion. *Id.* 230:5-7. Dr. Conti offers no literature to support her view of pharmaceutical pricing, and she barely even tries to justify it. The closest she could come was to analogize pharmaceutical pricing structures to collateral source payments received by individuals who suffer personal injuries in automobile accidents, claiming that "if I am injured in a car accident, if I receive side payments from my mother . . . that has nothing to do with the economic loss I suffered." *See* Conti Dep. I 195:2-12, 225:9-19.

Dr. Conti's litigation-driven focus on the point of sale ignores a host of factors that substantially affect the actual cost of medications. The first and most significant are government subsidies. These are particularly salient for benefit plans that provide coverage pursuant to Medicare, like Medicare Advantage Organizations putatively represented by the TPP class. These plans receive heavy government subsidies prior to the point of sale to cover the majority of their costs, and in some cases receive additional post-sale payments from the federal government pursuant to "risk corridors," i.e., if their aggregate spending exceeds the initial bid. *See* ECF 2010, Defs.' Mem. in Opp'n to Pls.' Mot. for Class Cert. of TPP Claims ("TPP Mem.") at

5-6, Apr. 12, 2022. Non-Medicare plans may also be subsidized by the government, such as through the federal Retiree Drug Subsidy. *Id.* at 6. Separate from government payments, various other fees may be credited after the point of sale, including payments based on performance guarantees. *See id.*

Dr. Conti's calculations of individual consumer damages suffer many of the same flaws. Like TPPs, consumers may receive post-sale refunds or credits. *See* Econ. Loss Mem. at 16; TPP Mem. at 6. For instance, some manufacturers (e.g., Mylan) and some pharmacies (e.g., Humana) offered full refunds for recalled VCDs. Econ. Loss Mem. at 7, 16. Moreover, the share of costs borne by individuals compared to their TPPs can be affected by post-sale coverage disputes, which would render the point-of-sale cost inaccurate. TPP Mem. at 6. Thus, even if Dr. Conti could reliably assign an economic value of zero to medications that were indisputably therapeutic—and she cannot—her calculation of liability damages for manufacturers and pharmacies would still be unreliable and inadmissible.

III. DR. CONTI'S PHARMACY-RELATED UNJUST ENRICHMENT OPINIONS ARE UNRELIABLE.

Dr. Conti's calculations for the Pharmacy Defendants use the same computational method for both liability theories and unjust enrichment: the sum of consumer payments for each state at issue. Conti Dep. II 49:11-50:24. Dr. Conti calculates what she calls "profits" by simply tallying patients' co-payments, without subtracting or offsetting any costs from those figures.

Dr. Conti agrees in theory that liability damages are different from the "profits" calculation she purports to make for unjust enrichment damages, *id.* 64:10-65:23, but she offers confusing formulas and sleight of hand in an effort to obscure the fundamentally unsound nature of her decision to use consumer payments as a substitute for pharmacy profits. Those efforts fail, and her unjust enrichment model should be excluded because it is internally inconsistent and contrary to basic economic principles.

A. Dr. Conti's Unjust Enrichment Model Is Internally Inconsistent.

The unreliable and results-driven nature of Dr. Conti's unjust enrichment model is made clear by her differential treatment of wholesalers and retail pharmacies. Dr. Conti posits six formulas (three each for wholesalers and pharmacies), each containing two definitions. Her unjust enrichment formula supposedly starts with the basic concept that "profits equals revenue minus costs." Conti Decl. ¶¶ 64, 82, Formulas 4 and 9. Although she defines "costs" similarly for Pharmacies and Wholesalers in her declaration,[9] both her deposition testimony and Plaintiffs' class certification briefing make it clear that she is treating Pharmacy

[9] Dr. Conti defines wholesaler costs as "the quantity of units of product *d*, distributed by the wholesaler over time period *t*," multiplied by "the average cost per unit of product *d*, distributed by the wholesaler over time period *t*." Conti Decl. ¶ 82, Formula 11. For pharmacy costs, her definition is "the quantity of units of product *d* sold to consumers over time period *t*" multiplied by "the average cost per unit of product *d*, over time period *t* to dispense to consumers." *Id.* ¶ 64, Formula 6.

Defendant costs differently from Wholesaler costs, because the only pharmacy costs she considers, even from a theoretical perspective, are "dispensing costs" at the point of sale. *See, e.g.*, Conti Dep. II 89:20-90:6 (agreeing from an academic perspective that she only wants to include "dispensing costs" in her unjust enrichment formula, which is different from "retailer costs"); ECF 1748, Pls.' Mem. in Supp. of Mot. for Class Cert. of Consumer Econ. Loss Claims at 107, Nov. 10, 2021 ("For Retailers, because they receive money at the point of sale, Dr. Conti calculates damages . . . at [the] point of sale . . . .").

Dr. Conti testified that for Wholesalers, "unjust enrichment is simply the amount of money made off of the transaction for moving drugs from one place to another net of cost." Conti Dep. II 127:8-10. In calculating this number, she would subtract "their cost of acquiring, storing, other offsets that they may have experienced . . . all of their costs." *Id.* 129:24-130:7 (cleaned up). Dr. Conti's proposed Wholesaler methodology would thus purportedly account for cost of purchase, *id.* 133:12-15, and for different non-product-related costs, *id.* 149:13-150:15.

Without explaining why, Dr. Conti focuses only on point-of-sale dispensing costs with respect to the Pharmacies, ignoring the very same sorts of costs, e.g., purchase and storage, that she acknowledges to be relevant to Wholesalers. Dr. Conti claimed that her profits calculation adequately accounted for certain costs because

the Pharmacies themselves removed dispensing "fees" from the data they produced about what consumers paid. Conti Dep. II 22:13-21; *see also id*. 50:3-7. In other words, because the data the Pharmacies produced in discovery did not include a column specifically listing out "dispensing fees," Dr. Conti assumed that: (1) all Pharmacies charged consumers a separate dispensing fee; (2) those dispensing fees were not included in the consumer payment amount on the Pharmacy spreadsheets; and (3) those dispensing fees demonstrate the actual costs of dispensing valsartan. These assumptions are factually wrong, *see* Kosty Rep. ¶¶ 184-189, and rest on a perceived misconception of what the Pharmacies were asked to produce. Beyond her personal experience of paying a dispensing fee for her own prescription, Conti Dep. II 97:15-19, Dr. Conti cites nothing to support her speculation that the "copay" listed within individual Pharmacy datasets excludes any dispensing fees, or that those dispensing fees accurately represent any pharmacy's costs.

At one point in her deposition, Dr. Conti incorrectly insinuated that either she or Plaintiffs' counsel had asked for and received "profits" data from the Pharmacy Defendants, which she reviewed. Conti Dep. II 176:6-8. But no Pharmacy Defendant produced "profits" data; nor were they required to do so. Dr. Conti did not review any discovery requests, responses, rulings, meet-and-confer correspondence, or pharmacy depositions to understand what the Pharmacy Defendants *actually* produced or were required to produce in discovery. *Id.* 13:4-14:17; Conti Decl.

Attachment B (list of materials relied upon).

Even if dispensing fees had been adequately accounted for, that would be just one small subset of each Pharmacy's cost structure, as it was for Wholesalers. Dr. Conti also failed to account for any other costs, even the most obvious ones, such as the cost of goods sold, which she believes to be irrelevant. Conti Dep. II 173:9-13 ("only thing" relevant is point of sale).[10] When given the opportunity to clarify or modify her opinion during her deposition, Dr. Conti confirmed that the Pharmacy Defendants' costs to purchase drugs were irrelevant to her calculation of profit. *Id.* 171:21-172:3 ("Q. [W]here in your report are you taking into account the fact that these pharmacies had to pay for the medication before they dispensed it . . . . A. That is of no moment in my analysis, sir."). Dr. Conti would not acknowledge that the Pharmacy Defendants incurred costs in procuring the drugs dispensed in this case, let alone that those costs should be included in a profit calculation:

> Q. Is it your understanding that the medication that you just referenced, stored in Walgreens' warehouse, had to be at one time purchased by Walgreens and stored in that warehouse?
> A. How is that of any moment to me, sir?
> Q. Is that a yes? I need to know. Do you agree that Walgreens would have to purchase the drug, or do you believe that they get it for free?

[10] Although Dr. Conti acknowledges the possibility of accounting for certain other costs—though not the cost of goods—in her so-called "profits" calculation, she offers no method for assessing what additional relevant costs would be, or how she or anyone attempting to calculate profits would begin to obtain them. Her "someone else can do this later" approach prevents this Court from determining that she has reliably applied principles to this case under Rule 702.

> A. It's not something, sir, that I considered – it's not in my report. Nowhere do I talk about the purchasing of these products by these retail pharmacies, because that is not of moment.

Id. 172:22-173:8; *see also id.* 93:18-96:5.

Beyond simply stating that only "point of sale" costs matter for the Pharmacy Defendants' profit calculation, Dr. Conti never explains *why* she treats Pharmacies and Wholesalers differently, or why she believes, even from a theoretical perspective, that the only costs that matter to a so-called "profits" calculation are those incurred precisely at the point of sale. This alone requires exclusion of her unjust enrichment opinions.

B. Dr. Conti's Unjust Enrichment Model Is Contrary To Basic Economic Principles.

Dr. Conti's unjust enrichment opinions should also be excluded because they are contrary to basic economics.

Expert testimony that disregards or conflicts with economic realities is inherently unreliable. In the antitrust context, for instance, the Third Circuit has emphasized that "an expert opinion generally must 'incorporate all aspects of the economic reality' of the relevant market." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012) (quoting *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000) (holding that district court erred in admitting expert testimony that was not grounded in economic reality)); *see Mosaid Techs. Inc. v. LSI Corp.*, No. 10-192-RGA, 2014 WL 12775325, at *1 (D. Del. Feb. 26, 2014)

(excluding testimony from damages expert after noting "the amount of damages should reflect consideration of the economic realities"); *Sherwin-Williams Co. v. PPG Indus., Inc.*, No. 17-1023, 2021 WL 4987937, at *2 (W.D. Pa. Oct. 27, 2021) ("Damages should be based on economic reality . . . .") (citation omitted).

One such economic reality is that profits are defined as revenue ***minus costs***. In theory, even Dr. Conti agrees. *See* Conti Decl. ¶ 64; Conti Dep. I 61:6-12 (explaining that unjust enrichment damages "would include . . . what the customer paid, what the third-party payor paid . . . minus the retailer costs"). Accordingly, an expert's profit analysis must include an evaluation of the *relevant* cost considerations to be admissible under *Daubert*. *E.g.*, *Richard Parks Corrosion Tech., Inc. v. Plas-Pak Indus., Inc.*, No. 3:10-cv-437(VAB), 2015 WL 5708541, at *5 (D. Conn. Sept. 29, 2015). In *Richard Parks*, the expert, like Dr. Conti, did not include any measure of costs in his calculations, and the court found this omission significant, holding that any calculation of profit "must include a consideration of what costs were or would have been, even if those costs are zero." *Id.* at *7 ("[N]et profit can be defined as the gross amount that would have been received pursuant to the business less the cost of running the business . . . .") (citation omitted). Thus, the court held that the expert's "lost profit" opinion was "inherently misleading" and "c[ould] not be cured properly on cross examination," requiring its exclusion under Rule 702. *Id.* at *5, *7.

Dr. Conti's unjust enrichment model for the Pharmacies suffers from the same flaws because her definition of "profit" at the "point of sale" has been pulled out of thin air. Although the exact calculation for unjust enrichment damages varies widely across jurisdictions, it may include either a restitution remedy or a disgorgement remedy. *See* ECF 1019, MTD Op. 6 at 27, Mar. 12, 2021. Disgorgement is measured in terms of "net profit," *S.E.C. v. Teo*, 746 F.3d 90, 106 (3d Cir. 2014) (quoting Restatement (Third) Restitution § 51(5)), and thus requires accounting for all revenues and costs that are "identifiable and measurable and not unduly remote," *id.* at 106 n.29 (citation omitted).

Despite being given multiple opportunities, Dr. Conti failed to demonstrate that her exclusion of the relevant costs accorded with generally accepted methodologies. Whether a given methodology has been generally accepted by the scientific community is "an 'important factor in ruling particular evidence admissible.'" *In re TMI Litig.*, 193 F.3d 613, 669 (3d Cir. 1999), *as amended* (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993)).

Dr. Conti could not identify any authority supporting the exclusion of relevant costs, such as cost of goods, from her so-called "profit" calculations. Conti Dep. II 177:9-179:7 (failing to identify treatises, articles, or scientific literature stating that costs of acquiring a drug can be excluded from a pharmacy's profits); *see also* Stiroh Dep. 232:6-13 ("Q. Have you ever seen an economics textbook or scholarly piece of

literature, or anything like that, where someone measures profits from an economics perspective without considering the cost of ingredients? A. No. For the highest level with no detail, to say that profits are revenue minus cost, it still has cost.").

In short, Dr. Conti has created a model for so-called "profits" that is untethered to any recognized methodology and unsupported by any literature. *Cf. United States v. Frazier*, 387 F.3d 1244, 1263 (11th Cir. 2004) ("[E]xpert testimony may be assigned talismanic significance in the eyes of lay jurors, and, therefore, the district courts must take care to weigh the value of such evidence against its potential to mislead or confuse."). This, too, requires exclusion of her unjust enrichment opinions.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Conti's opinions purporting to calculate damages attributable to the Manufacturer and Pharmacy Defendants in their entirety.

Dated: May 3, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 3, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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